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Michelle D. Hines

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AVON PRODUCTS, INC.

AVON PLACE

SUFFERN, NY 10901

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

08/20/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENT.DEPARTMENT@AVON.COM

DETAILED ACTION

Applicant's response filed on 5/14/2008 is acknowledged. Currently, claims 23-27 are pending.

Applicants argue over the 35 USC 103 rejection that the rejection is deficient because there is no rationale why one would be motivated to modify the compounds of Wagle to arrive at the claimed compound. Applicants further argue that 2-amino-4,5-dimethylthiazole is not obvious over 2-amino-5-methylthiazole or 2-amino-4-methylthiazole because the unpredictability in the art would have precluded one from concluding that the instantly claimed compound has similar properties to Wagle's. Applicant's also state that it is on the record that the art is "an unpredictable and undeveloped art" in connection with an enablement rejection. Applicants then state that the state of the art would have precluded a reasonable expectation that the claimed compound would have similar properties to Wagle's compounds and then give arguments that the literature shows that binding of 2-amino-4,5-dimethylthiazole is not obvious over 2-amino-5-methylthiazole or 2-amino-4-methylthiazole and one would not assume that these compounds have similar properties.

In response to the above arguments, it is stated in the MPEP § 2144.09 that a "prima facie" case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities". It is further stated that "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313,

203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).

The MPEP further teaches that homologs include compounds differing by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups. Furthermore, the composition of the present application is for cosmetic use and it is intended to be applied to the skin for improving the texture and elasticity of the skin (as taught in the specification). The compositions taught by Wagle et al. are intended for improving the elasticity or reducing wrinkles of the skin (paragraph 0007). Therefore, considering the art as a whole, there is a prima facie case of obviousness because of the close structural similarity between the present composition and the composition of the prior art, there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious). Further, Applicants previously claimed a compound having various substitutions of which would change the structure of the compound. Because Applicant's showed data for one compound (2-amino-4,5-dimethylthiazole), data was not provided for all compositions that were being claimed and this what the enablement rejection was addressing.

The rejections are given below for Applicant's convenience.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Wagle et al. (US Pg-Pub 2002/0022622) in view of Gould (Int J Pharmaceutics, 33 (1986) 201-217).

Wagle et al. teaches pharmaceutical compositions that meet the limitation of the 2-amino-4,5-dimethylthiazole of claim 1. In particular, Formula I in paragraph 0004 corresponds to 2-amino-4,5-dimethylthiazole when J is sulfur, R^a and R^b are alkyl and R is amino (meeting the limitations of claim 23). Though this particular compound is not stated within the reference, two closely related compounds are specifically stated which are 2-amino-5-methylthiazole and 2-amino-4-methylthiazole. It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Lincoln, 126 U.S.P.Q. 477, 53 U.S.P.Q. 40 (C.C.P.A. 1942). The compositions are further formulated with pharmaceutically acceptable salts (meeting the limitation of claim 23-26; paragraph 0125, 0248, and claim 1).

Wagle et al. do not specifically teach the hydrochloride salt or the weight percentages of the composition.

Gould et al. teaches that salt formation provides a means of altering the physicochemical and resultant biological characteristics of a drug without modifying its chemical structure and teaches that hydrochloride is an FDA-approved commercially marketed salt (Table 1).

Furthermore, it is obvious to vary and/or optimize the amount of 2-amino-4,5-dimethylthiazole provided in the composition, according to the guidance provided by Wagle et al., to provide a composition having the desired properties such as the desired percentages that will effectively treat a disease or a condition. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is respectfully pointed out that the recitation “cosmetic composition for topical application to the skin for inhibiting glucose oxidase” and “wherein said 2-amino-4,5-dimethylthizaole or salt thereof is present in an effective amount for inhibiting glucose oxidase when applied topically to the skin” in claim 23 has not been given patentable weight because the recitation occurs in the preamble and the intended use is not afforded patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951). Furthermore, the claims are being

treated as composition claims and the intended use of the composition is not afforded patentable weight.

According to the teachings of Wagle et al., it would be obvious to formulate a composition comprising 2-amino-4,5-dimethylthiazole because Wagle et al. teaches compounds that differ from the presently claimed composition by only a methyl group. Accordingly, it would be obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Wagle et al. with Gould et al. because Gould et al. teach that hydrochloride is an FDA-approved commercially marketed salt. One would be motivated to modify the compounds of Wagle et al. with a reasonable expectation of success because the compounds are all taught for treating skin elasticity. One would be motivated to combine the references and add the hydrochloride salt to 2-amino-4,5-dimethylthiazole in an effort to stabilize the compound.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617